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York v. **American Medical Systems**, Inc.
C.A.6 (Ohio),1998.
NOTICE: THIS IS AN UNPUBLISHED OPINION.(The Court's decision is referenced in a "Table of Decisions Without Reported Opinions" appearing in the Federal Reporter. Use FI CTA6 Rule 28 and FI CTA6 IOP 206 for rules regarding the citation of unpublished opinions.)
United States Court of Appeals, Sixth Circuit.
Robert **YORK**, Plaintiff-Appellant,
v.
AMERICAN MEDICAL SYSTEMS, INC., Defendant-Appellee.
No. 97-4306.

Nov. 23, 1998.

On Appeal from the United States District Court for the Southern District of Ohio.

Before MERRITT and COLE, Circuit Judges; EDMUNDS,[FN*] District Judge.

FN* The Honorable Nancy G. Edmunds, United States District Judge for the Eastern District of Michigan, sitting by designation.

OPINION

COLE, Circuit Judge.
***1** Plaintiff, Robert **York**, appeals the district court's grant of summary judgment in favor of the Defendant, **American Medical Systems**, Inc., in this action alleging violations of the Ohio Product Liability Act, Ohio Revised Code ("O.R.C") §§ 2307.71-2307 .78. On appeal, **York** makes three claims of error. First, **York** claims that the district court erred in granting American Medical System's motion for a protective order. Second, **York** claims that the district court erred in granting summary judgment in favor of **American Medical Systems**. Finally, **York** alleges that the district court erred in excluding the testimony of Dr. Feinberg, **York's** expert. For the following reasons, we AFFIRM the district court's decisions.

BACKGROUND

American Medical Systems manufactures a variety of penile prostheses or penile implants. These implants are primarily used to treat organic impotence or the inability of a patient to obtain and maintain penile erection. Among its products is the AMS 700CX inflatable penile prosthesis ("700CX"). The 700CX consists of three primary components: (1) a pump that is implanted in the scrotum, (2) a spherical reservoir that is placed in the patient's lower abdomen and (3) two tubing cylinders that are implanted in the penis. The main feature of the 700CX is that it permits the patient to inflate and deflate the implant by manipulating the pump. Once the patient manipulates the pump, the pump transfers fluid from the reservoir to the cylinders that inflate to simulate an erection.

On January 23, 1990, Peter Wakefield, M.D.,[FN1] implanted a 700CX in Robert **York**. In November 1991, less than two years after implantation of the 700CX, **York** reported that he could not achieve a full erection with the implant. Once he tested the device, Dr. Wakefield observed that the pump worked nicely up to a point before running out of fluid. Dr. Wakefield attributed the complication to a possible leak somewhere in the system. Because the implant as a whole functioned well, however, and because **York** wished to avoid surgery if he could, Dr. Wakefield decided to reevaluate the prosthesis at a later date.

FN1. Dr. Wakefield was deceased at the time of this lawsuit.

At some point between 1991 and March 1995, **York's** prosthesis completely stopped working. It was then that **York** first consulted with Daniel

Kessler, M.D., a urologist. During his initial visit, **York** reported that the 700CX stopped working and, as a result, he was unable to have intercourse. Concluding that the prosthesis was not operating properly, Dr. Kessler performed surgery to fix it.FN2Based on his examination of the prosthesis, Dr. Kessler concluded there was a slow leak in the prosthesis resulting from a pinpoint hole in the left cylinder. Because the leak was slow, Dr. Kessler opined that the implanting surgeon would not have discovered such a leak by performing normal preoperative testing. **York** continued to have problems with the prosthesis even after the surgery.

> FN2. During the surgery Dr. Kessler removed the pump and cylinders but decided to reuse the reservoir.

On December 5, 1994, **York** filed a complaint in the United States District Court for the Southern District of Ohio based on diversity jurisdiction. **York** alleged several causes of action. First, **York** alleged that he was injured-that he suffered pain and had to undergo subsequent reconstructive surgery-because **American Medical Systems** negligently manufactured and tested its 700CX. Specifically, **York** alleged that the particular 700CX implanted in him had a manufacturing defect because it deviated in a material way from the design specifications. Additionally, **York** alleged that **American Medical Systems** failed to warn him of certain defects and risks associated with use of the 700CX. Finally, **York** alleged that **American Medical Systems** breached its express warranty and implied warranty of merchantability FN3 with respect to the 700CX penile implant.

> FN3. Plaintiff has also dropped this allegation from its appeal.

***2** In response to **York's** discovery request, **American Medical Systems** filed a motion for a protective order to prevent disclosure of Medical Device Reporting documents ("MDRs"), including the complaint and analysis documents, in unredacted form. Specifically, **American Medical Systems** sought to redact or withhold the names of patients, physicians and hospitals contained in those documents. Relying on Federal Regulations promulgated by the Food and Drug Administration ("FDA"), specifically 21 C.F.R. § 803.1(a)*et seq* . and 21 C.F.R. § 20.63, the district court granted the request and ordered disclosure of the documents in redacted form.

American Medical Systems also moved to disqualify **York's** expert, Dr. Barry Feinberg. The district court granted the motion, holding that Dr. Feinberg did not qualify as an expert on penile implants. Considering his background in mathematics and electrical engineering, the court concluded that Dr. Feinberg did not qualify as an expert and, accordingly excluded his testimony.

Following its disqualification of Dr. Feinberg, the court granted American Medical System's motion for summary judgment. The court concluded that **York** failed to provide any evidence that the leak and subsequent difficulties with the 700CX were proximately caused by the conduct of **American Medical Systems** or were attributable to **American Medical Systems** in any way. This timely appeal followed.

On appeal **York** raises three issues. First, he claims that the magistrate judge erroneously granted a protective order permitting **American Medical systems** to redact the names of patients, physicians, and hospitals from the MDRs. Second, he claims that the district court erred in granting summary judgment in favor of **American Medical Systems** when genuine issues of material fact existed as to whether **American Medical Systems** was responsible for the leak found in **York's** prosthesis. Finally, **York** claims the district court abused its discretion by excluding the testimony of Dr. Feinberg on the basis that he was not an expert with respect to penile prostheses.

I. Protective Order

York claims that the magistrate judge's grant of a protective order permitting **American Medical Systems** to redact the names of all patients, physicians and hospitals from the MDRs submitted to the FDA constituted an abuse of discretion. We uphold the magistrate judge's grant of a protective order on two separate grounds: first, the language of the provisions does not permit disclosure of the requested information; and second, the magistrate judge's decision was well within the magistrate judge's discretion.

To promote the cooperation of manufacturers with the FDA in regulating the safety of medical devices and drugs, the FDA has promulgated regulations that protect the confidentiality of physicians and patients associated with MDRs. Though the FDA has discretion to disclose MDRs, it is required to delete information that would compromise privacy interests. Specifically, 21 C.F.R. § 803.9 provides in part:

***3** (a) Any report, including any FDA record of a telephone report submitted under this part is available for public disclosure in accordance with part 20 of this chapter.

(b) Before public disclosure of a report, FDA will delete from the report.

(2) Any personal, medical, and similar information ... which would constitute an invasion of privacy.

(3) Any names or other identifying information of a third party voluntarily submitting an adverse event report.

With respect to voluntary reporters, 21 C.F.R. § 20.63 provides:
(a) The names or other information which would identify patients or research subjects in any medical or similar report, test, study, or other research project shall be deleted before the record is made available for public disclosure.

(f) The names and any information that would identify the voluntary reporter or and other persons associated with an adverse event involving a human drug, biologic, or medical device product shall not be disclosed by the [FDA] or by a manufacturer in possession of such reports in response to a request, demand, or order. Information that would identify the voluntary reporter or persons identified in the report includes, but is not limited to, the name, address, institution, or any other information that would lead to the identities of the reporter or persons identified in a report. This provision does not affect disclosure of the identities of reporters required by a Federal statute or regulation to make adverse event reports.

There are, however, exceptions that permit disclosure of the identities of parties associated with adverse events. Identities may be disclosed if both the voluntary reporter and the person identified in the report consent in writing to disclosure. Additionally, the identities of the voluntary reporter and the person who experienced the reported adverse event may be disclosed pursuant to a court order in the course of medical malpractice litigation involving both parties. *See*21 C.F.R. § 20.63(1)(I)(ii).

The FDA recognized that the documents it holds provide a treasure trove of information for products liability litigants. Considering the possibility that courts may require disclosure of confidential information, the FDA enacted 21 C.F.R. § 20.83, which permitted disclosure by the FDA in compliance with a final court order. Title 21 C.F.R. § 20.86 went a bit further and permitted disclosure of confidential information during FDA proceedings or other court proceedings. The information may be disclosed only when it is relevant, and the FDA is required to take the necessary precautions to ensure that it discloses no more information than is necessary under the circumstances. *See*21 C.F.R. § 20.86.

York argues that when read together, §§ 20.86 and 20.83 required the magistrate judge to deny **American Medical Systems's** request for a protective order. According to **York**, those sections require manufacturers to disclose confidential information protected by § 20 .63 pursuant to a court order.

American Medical Systems responds that **York's** interpretation of §§ 20.83 and 20.86 would nullify § 20.63. **York's** argument undermines the entire framework of confidentiality upon which the FDA voluntary reporting system is based. Considering **York's** argument, every court could, in effect, with the stroke of a pen require manufacturers to reveal confidential information of third parties.

***4 American Medical Systems's** argument has merit. We interpret § 20.63 as granting a blanket prohibition against disclosure of confidential information by manufacturers, subject to the exceptions contained in § 20.63. Sections 20.83 and 20.86, based on their language, carve out a limited exception for the FDA, not manufacturers, to disclose documents in its possession. Our interpretation is based on the following reasoning.

First, the language of the provisions supports this interpretation. Specifically, § 20.83(a) states that the records subject to the provision are those held by the FDA. In § 20.63, the language of the provision explicitly refers to the voluntary reporter of the information. If § 20.83 applied to manufacturers, physicians and other voluntary reporters it would have, at a minimum, mentioned those parties.

Second, both §§ 20.83 and 20.86 place the onus of identifying the individuals whose privacy may be breeched and the responsibility of tailoring disclosure to the minimum required by the FDA or court proceedings on the FDA, not on manufacturers. It makes sense to require manufacturers and other reporting parties to undertake the same responsibilities as the FDA in controlling disclosure if they were also subject to these provisions.

More important, the legislative history of § 20.63 supports this construction of the provisions. Specifically, the comments to § 20.63 state that the provision allowed for disclosure only in the situations outlined in the exceptions. Furthermore, the provision contains a broad preemption section which prohibits states and local agencies from enacting or enforcing laws requiring disclosure that are inconsistent with § 20.63.

Under § 20.63, disclosure is permitted pursuant to court order only when both the manufacturer and the party experiencing the adverse event are involved in the litigation. From this, it follows that only parties involved in the **York** litigation may petition the court for a court order requiring **American Medical Systems** to disclose its MDRs relating to the **York** litigation, not MDRs relating to parties not involved in **York's** case. Accordingly, the magistrate judge did not err in granting the protective order.

Moreover, Federal Rule of Civil Procedure 26(c) grants broad discretion to trial judges in fashioning protective orders. *See In Re Eli Lilly & Co.,* 142 F.R.D. 454, 456 (S.D.Ind.1992). A motion under Rule 26(c) to limit discovery requires the district court to balance the interests at issue, and to compare the hardship on both parties if the motion is either granted or denied. *See id.*In making its determination, the court must consider the nature and magnitude of the hardship imposed on each party by the order. *See id.*

The magistrate judge considered the relevant hardships the protective order or denial of the protective order would impose on **York** and **American Medical Systems**. **York** provided no statement or support for any hardship he would suffer from the grant of protective order. Apart from inconvenience in seeking the information from the FDA or through other means, **York** did not state 1) why the information is essential to his case, and 2) why **American Medical Systems** is the only source of that information.

***5** In contrast, **American Medical Systems** has a key policy concern on its side. The entire reporting scheme of the FDA is based on confidential reporting by manufacturers, physicians, and patients. To encourage voluntary reporting, it is necessary to ensure reporters that their information will be kept in confidence and not cavalierly disclosed in various litigation. Requiring **York** to demonstrate a severe

hardship as a justification for subverting such an important policy interest is reasonable. **York** has failed to do so.

The magistrate judge did not abuse his discretion in granting the protective order; accordingly, we affirm the magistrate's decision.

II. Summary Judgment

Summary judgment is proper when the district court determines that the pleadings, affidavits, and other submissions present no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. *See*Fed.R.Civ.P. 56(c). Because summary judgment effectively denies a party his "day in court," courts must grant it with extreme caution. *See Smith v.. Hudson,* 600 F.2d 60, 63 (6th Cir.1979). Accordingly, when reviewing a motion for summary judgment, the court must view the evidence in the light most favorable to the nonmoving party. *See United States v. Diebold, Inc.,* 369 U.S. 654, 655, 82 S.Ct. 993, 8 L.Ed.2d 176 (1962).

To defeat a summary judgment motion there must be more than the allegation that a factual dispute exists. *See Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). Rather, the nonmoving party must go beyond the pleadings and designate specific facts showing that there is a genuine factual dispute which requires a trial. *See id.* at 250."No genuine issue of fact exists where there is a complete failure of proof concerning an essential element of the nonmoving party's case."*Celotex Corp. v. Catrett,* 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). In this situation, the moving party is entitled to judgment because the nonmoving party has not provided evidence on an essential element of the case. *See id.*

The district court granted **American Medical Systems's** motion for summary judgment because it concluded that **York** failed to provide evidence to support the elements of his claims. We agree. **York** alleged several causes of action, each of which required that **York** prove that the malfunctioning of the 700CX penile prosthesis was attributable to **American Medical Systems**. Because **York** failed to provide proof as to the cause of the defect in the prosthesis, an essential element of his claims, summary judgment was proper.

First, **York** alleges that **American Medical Systems** negligently manufactured the 700CX penile implant he received, and that **American Medical Systems** negligently tested the device because it failed to discover that the prosthesis deviated from design specifications. To establish a claim for negligent manufacture, **York** must prove that: (1) the prosthesis was defective in manufacturer and construction; (2) that it deviated in a material way from the design specifications, formula or performance standards for the 700CX; and (3) that the deviation existed when **American Medical Systems** delivered the prosthesis to the implanting surgeon. *See*O.R.C. § 2307.74.

***6 York** argues that the prosthesis was defective because it leaked. According to **York**, Dr. Kessler's testimony and Dr. Feinberg's experiments establishing that there was a hole in one of the cylinders of the prosthesis raise a genuine issue of material fact as to whether that hole was caused by **American Medical Systems**. **York's** argument is without merit. Whether there is a hole in the prosthesis does not shed much light on what caused the hole. **York** must provide some evidence that the hole existed through some fault of **American Medical Systems**. Though Dr. Kessler speculated that it could have existed at the time it was implanted, he did not provide a definitive expert opinion that the hole did in fact exist at that time. Such a speculative answer would not be evidence that a leak existed at the time **American Medical Systems** tendered the prosthesis to the implanting physician. Likewise, if admissible, Dr. Feinberg's testimony fails to provide evidence that the hole existed be-

cause of **American Medical Systems's** negligence. **York's** failure to provide such evidence to create a material issue of fact as to whether **American Medical Systems** is responsible for the hole is fatal to his claim. Accordingly, the district court's grant of summary judgment on this claim was appropriate.

York's negligent testing claim must also fail. **York** was required to prove that **American Medical Systems** failed to test the prosthesis adequately and, because **American Medical Systems** failed to do so, it did not detect the defect or hole in the prosthesis. To defeat summary judgment on this claim, **York** was required to produce evidence that **American Medical Systems** caused the hole or that it existed when **American Medical Systems** tendered the prosthesis. Because **York** has failed to do so, the district court's grant of summary judgment on this claim was proper.

York's remaining claims likewise fail. His failure-to-warn claim has two parts. First, **York** claims that **American Medical Systems** failed to warn him of the hole or the folds that could develop with the prosthesis. Second, **York** claims that **American Medical Systems** did not warn him of defects after he purchased the prosthesis once **American Medical Systems** received and was aware of complaints by other customers that the 700CX malfunctioned. Neither claim has merit.

First, O.R.C. § 2307.76 provides that a product is defective due to inadequate warnings when (1) the manufacturer knew of risks or should have known of risks associated with the product that allegedly caused the harm, and (2) failed to provide the warnings that a manufacturer exercising reasonable care would have. **York** fails to meet this test. **American Medical Systems** provided warnings about the possibility of folds developing and the possibility of leakage. Specifically the product literature provided: “Mechanical complications may include ... leakage of fluid.... Oversizing leads to cylinder folds that may compromise cylinder life.” **York** claims that **American Medical Systems** failed to provide adequate warnings about these precise defects. Specifically, he argues that the warnings it provided regarding folds did not explain that the prosthesis could develop folds and leaks even when not in use. According to **York**, a warning is inadequate unless it discloses all risks associated with the use of a product. *See Seley v. G.D. Searle & Co.*, 67 Ohio St.2d 192, 198, 423 N.E.2d 831 (1981). He argues that because **American Medical Systems** failed to warn about the possibility of leaks and folds developing when the product was not in use, its warnings were inadequate.

***7** The warnings **American Medical Systems** provided, however, specifically addressed the possibility of leakage and the development of folds. Although the warnings did not specifically address **York's** theory on how the leak and the folds developed, the warnings addressed the development of folds and the possibility of leaks. We do not believe that **American Medical Systems** did not act as a reasonable manufacturer would in providing those warnings. *See id.* at 199, 423 N.E.2d 831.

Similarly, **York's** claim that **American Medical Systems** failed to provide warnings after the sale of the prosthesis is without merit. Under O.R.C. § 2307.76(A)(2), a manufacturer is liable for failure to give post-market warnings when after the sale the manufacturer becomes aware of defects and fails to provide warnings about those defects that a manufacturer exercising reasonable care would have. **York's** argument is based on complaints made after the sale of his prosthesis that the implant leaked fluid. **American Medical Systems** provided warnings about leakage and folds before the sale. Thus, because it has already provided a warning that the prosthesis is prone to leakage, providing post-market warnings that it received complaints that the 700CX leaked would serve little purpose. The post market warning provision is simply inapplicable here. Such a requirement is necessary when the manufacturer becomes aware of a defect or risk

about which it did not previously warn customers. Accordingly, the district court appropriately granted summary judgment to **American Medical Systems** on this claim.

Additionally, **York** alleged that **American Medical Systems** breached its express warranty that the 700CX would provide excellent prosthetic erections. To prevail, **York** was required to show that the product is defective because it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer. It is debatable whether **American Medical Systems's** statement that the 700CX would provide excellent penile erections is no more than puffery. Even if it were considered a valid warranty, **York** has not provided any evidence that the prosthesis failed to provide excellent prosthetic erections or ensure a flaccid penis when it left the control of the manufacturer. **York** must provide some evidence that the failure is attributable to **American Medical Systems** in some way. Because he has failed to do so, the district court appropriately granted summary judgment on this claim. Considering that **York** has failed to provide any evidence suggesting that **American Medical Systems** caused the leak in **York's** prosthesis, we affirm the district court's grant of summary judgment in favor of **American Medical Systems** on **York's** products liability claims.

III. Expert Witness

This Court reviews a district court's decision to admit or exclude expert testimony under an abuse of discretion standard. *See General Electric Co. v. Joiner*, 522 U.S. 136, 118 S.Ct. 512, 518, 139 L.Ed.2d 508 (1997). Under the abuse of discretion standard, a trial court's decision is accorded great deference. Unless the reviewing court has a definite and firm conviction that the trial court committed a clear error of judgment, the lower court's decision stands. *See Logan v. Dayton Hudson Corp.*, 865 F.2d 789, 790 (6th Cir.1989).

***8** The district court determined that Dr. Feinberg was not qualified to testify as to the issue of whether the penile prosthesis was defective. Because we conclude that the testimony of Dr. Feinberg does not provide any evidence on the critical issue of causation we need not reach the issue of whether the district court erred in excluding his testimony.

CONCLUSION

For the foregoing reasons we AFFIRM the district court's grant of summary judgment in favor of **American Medical Systems**, and AFFIRM the magistrate judge's grant of a protective order to **American Medical Systems**.

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